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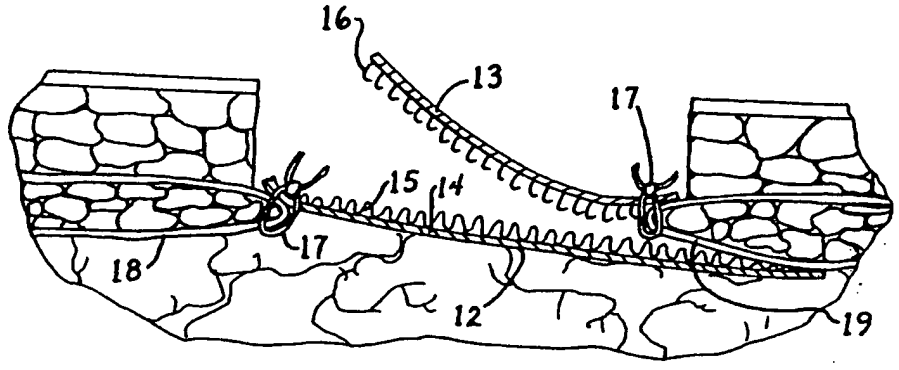
(54) Title: WOUND CLOSING METHOD AND DEVICE



(57) Abstract

A kit for temporarily closing an abdominal incision consists of a package containing two sterile sheets (12, 13) with surfaces (15, 16) that releasably mate. The sheets are trimmable and can be sutured to the edges of an incision with conventional operating room equipment. A method of temporarily closing an incision using the kit elements also is disclosed.

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WOUND CLOSING METHOD AND DEVICE

The present invention generally relates to a wound closing method and device. More particularly, it relates to a method and device for the temporary closing of a wound in such a manner that it can be opened and closed repeatedly.

There are a number of abdominal surgery procedures, especially for trauma and emergency conditions, which cannot be solved with a single operation and multiple re-operations are required. Traditionally, the surgeon was re-operating when clinically the need for a re-operation became obvious. This, however, caused a delay in diagnosis which consequently resulted in a high mortality in such conditions.

To avoid the delay in diagnosis of postoperative intraabdominal emergencies the conception of planned relaparotomy was designed; and, in some cases, the abdominal cavity was left open. This, however, was complicated by fistula formation and huge abdominal incisional hernias. On the other hand, when temporary closure with retention wires was used severe abdominal wall necrosis and necrotizing fasciitis were observed.

There is obviously a need for a method and device for temporary wound closure to ease relaparotomies. Various methods and devices have been proposed and used. One such method involves suturing a zipper or plastic glider

to the cut ends of the subserous fascia at opposed edges of the wound. The zipper or glider is opened to expose the peritoneal cavity and closed to close the wound. Unfortunately, the plastic gliders used can pop open by themselves with minimal tension. The use of metal zippers solved that problem, but they, like the glider, were not totally satisfactory since the size of the abdominal opening had to be adapted to the varying volumes of intraabdominal organs and pressure to avoid tissue damage and to decrease the risk of pulmonary and renal insufficiency. These complications are associated with increased intraabdominal pressure. Additionally, the approximation of the fascia should be aimed as early as possible in order to avoid retraction of fascial and formation of incisional hernias. Due to the decreasing inflammatory edema as treatment progresses, a zipper or glider has to be replaced by a similar member with a smaller cloth side. In some cases replacements were necessary for more than 4 times as shown in a series of 100 cases of planned multiple re-operations.

A need exists for a simple, effective, improved method and device for use in opening and closing incisions and eliminating the need for relaparotomies.

The objects of the present invention are to disclose a simple, effective, improved method and device for the temporary closing of a wound or incision so that it can be subsequently opened and reclosed as needed.

The device of the present invention basically comprises a kit which comprises two flexible, trimmable sterile sheets packaged in a sterile container. The first, flexible, trimmable sheet has a relatively smooth bottom for covering the wound, and a top surface which will mate with or form a bond with the bottom surface of the second, flexible, trimmable sheet.

In the preferred embodiment the kit consists of a sterile package containing two sterile rectangular sheets of plastic Velcro material, each about 16 x 25 cm. One

sheet is characterized by having "hooks" on the bottom, while the other sheet has a top with "loops" to which the "hooks" attach when the two pieces are placed one upon the other with the "hooks" on the "loops". Once thus joined the sheets can only be disconnected by lifting and separating one sheet from the other. They cannot be separated by pulling the sheets apart edge to edge.

In the methods of the present invention, one edge of the first sheet is sutured to the abdominal wall fascia along one edge of an incision or wound with the top of the sheet with its mating surface ("loops") facing upward, and the relatively smooth bottom facing downward. The first sheet preferably extends from one lateral edge of the fascia to the other side of the wound to provide maximum protection. The second flexible, trimmable sheet is then sutured to the opposite fascia of the abdominal wound with the bottom mating surface ("hooks") facing downward. To temporarily close the wound a pulling pressure is exerted on each of the two sheets to pull the fascia under tension, and the mating surfaces are brought together to close the incision. Intraabdominal organs may be protected during the process by covering the mating surfaces of the second sheet with a towel, as long as the abdomen is open.

Subsequently, when the planned re-exploration and repair of the abdomen is performed, the bonds between the mating surfaces are broken and the sheets folded back to open the previously closed wound. If the wound is to be again temporarily closed, the process is reversed taking care to insure that both abdominal wall fasciae are again under tension so that they do not retract. When the wound is reclosed, the edges of the fasciae are closer together than originally and the unnecessary material of the sheets can be trimmed off and removed. The opening and closing can be repeated until the wound is ready to be permanently closed by a continuous suture.

The novel method of the present invention is cost effective as it better uses hospital resources and it reduces both mortality and morbidity.

It will be apparent to those skilled in the art that the present invention fulfills the above-stated objects and also provides other advantages.

In the drawings:

Fig. 1 is a perspective view of a kit of the present invention;

Fig. 2 is a perspective view showing the present invention closing an abdominal incision;

Fig. 3 is a view taken along lines 3-3 in Fig. 2;

Fig. 4 is another view like Fig. 2 showing the device of the invention being trimmed with scissors to remove excess material;

Fig. 5 is a view like Fig. 2 showing the abdominal incision closed after trimming; and,

Fig. 6 is a perspective view of another embodiment of the kit of the present invention.

In the preferred embodiment of the invention shown in Fig. 1, the kit 10 includes a sealed outer package 11 with a sterile interior which contains a sterile female sheet 12 and a sterile male sheet 13.

As seen in Fig. 3, the female sheet 12, has a smooth bottom 14, and a top 15, which is adapted to mate with the bottom 16, of the male sheet 13. When the sheets 12 and 13, are of Velcro, the top 15, of the female sheet 12, is covered with a fuzzy, "looped" surface and the bottom 16, of the male sheet 13, is provided with a multitude of "hook-like" protuberances that mate with the fuzzy, looped surface to releasably bond the sheets together.

The sheets 12 and 13 should be made of a biocompatible, easily sterilized fabric which can be easily and securely sutured, and easily trimmed using conventional operating room instruments. Preferably, the sheets 12 and 13 are of a polyester material, and they are of contrasting colors to avoid confusion.

The preferred method of the present invention now will be described in conjunction with Figs. 2 to 5.

When it is desired to close an incision, as for example at the end of a laparotomy, one edge of the female sheet 12, is attached with sutures 17, to one fascia 18 with the top or "fuzzy" side 15 up, i.e., so that the "fuzzy" side does not contact bowel wall, omentum, or other intraperitoneal organs. One edge of the male sheet 13, which is preferably of a contrasting color, is sutured to the opposite fascia 19 so that the bottom or "hooks" side 16 will face toward the top or "fuzzy" side 15 of sheet 12, which is covering the abdominal organs. Then the fascial edges are approximated by pulling the free edges of both of the sheets 12, and 13 toward each other until they can be adhered or bonded across the incision. Intraabdominal organs may be protected during this process by covering the bottom or "hook" side 16 with a towel as long as the abdomen remains open.

In Fig. 3, the sheets 12 and 13 can be seen overlapped and bonded together by the mating of the Velcro top 15, and bottom 16. When thus mated the sheets 12 and 13 cannot be separated except by lifting the male sheet 13 off of the female sheet 12. Re-operation may be conducted on a 24 hour schedule or any other planned or required interval.

When the edges of the incision can be brought closer together, the excess material of the sheets 13 and 12 can be trimmed as shown in Fig. 4, and the incision reclosed as seen in Fig. 5.

In Fig. 6, another embodiment of the kit is shown in which the sheets 12' and 13' are provided with means for fascilitating suturing such as the row of apertures 20. After the last procedure is completed the incision can be closed by continuous suture through the fasciae using a monofil nylon string. No drains are usually required

It will be readily apparent to those skilled in the art that a number of changes and modifications can be made without departing from the spirit and scope of the present invention. Therefore, it is intended that the invention be limited only by the claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are as follows:

1. A kit for repeatedly closing and opening a wound, said kit comprising:

(a) a closed, internally sterile package;

(b) a first trimmable, sterile, flexible sheet in said package, said first sheet and having a smooth bottom and a top provided with a mating surface;

(c) a second trimmable sterile, flexible sheet in said package, said second sheet having a bottom provided with a surface that will mate with the mating surface of the top of the first sheet to form a releasable and resealable bond, said bond being strong enough to prevent the abdominal fasciae on the edges of the wound from retracting.

2. A kit of claim 1 in which the mating surface on the first sheet comprises a plurality of female loops, and the mating surface on the second sheet comprises a plurality of male projections.

3. A method of temporarily closing an abdominal incision so that it can be opened and then closed again with a minimum of trauma, said method comprising:

(a) attaching one edge of a sterile, flexible sheet having a top with a first mating surface to the fasciae at one edge of an incision with the first mating surface extending upwardly;

(b) attaching one edge of a second sterile, flexible sheet having a bottom with a second mating surface that mates with said first mating surface to the fascia at another edge of said wound;

(c) pulling on first and second sheets to put a positive tension on the fasciae at the edges of the incision; and

(d) forming a releasable, resealable bond between the first and the second mating surfaces.

4. The method of claim 1 in which the first mating surface includes a plurality of loops and the second mating surface includes a plurality of hooks that enter into and are retained by said loops.

5. A kit for repeatedly closing and opening a wound, said kit comprising:

(a) a first sterile flexible, trimmable, sheet, said sheet having one edge thereof for attachment to the along one edge of a wound, said sheet also having a biocompatible bottom and a top with a mating surface;

(b) a second sterile flexible, trimmable, second sheet, said sheet having one edge thereof for attachment of the abdominal fascia along another edge of said wound, said sheet having a bottom with a mating surface which cooperates with the mating surface of the first sheet to form a releasable, resealable bond and to maintain a pulling tension on the abdominal fasciae so that they do not retract; and,

(c) sterile packaging means protecting said first and second sheets from contamination.

FIG. 2

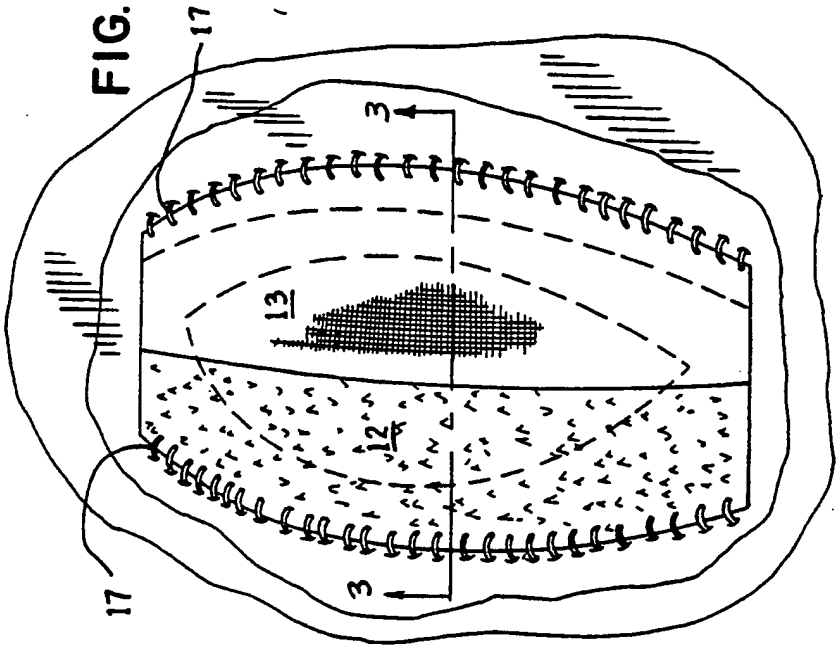


FIG. 3

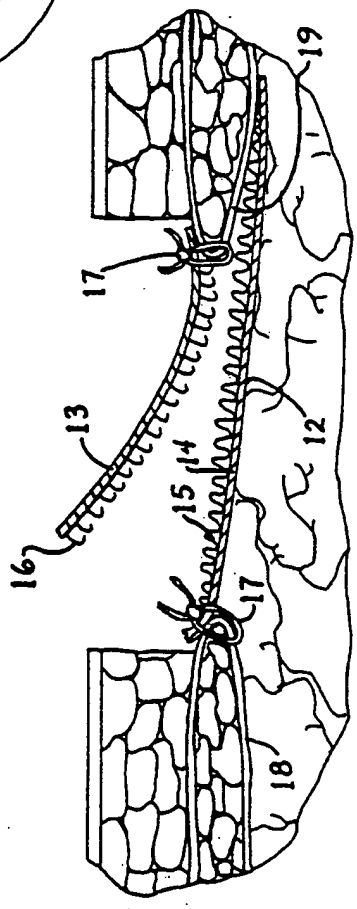
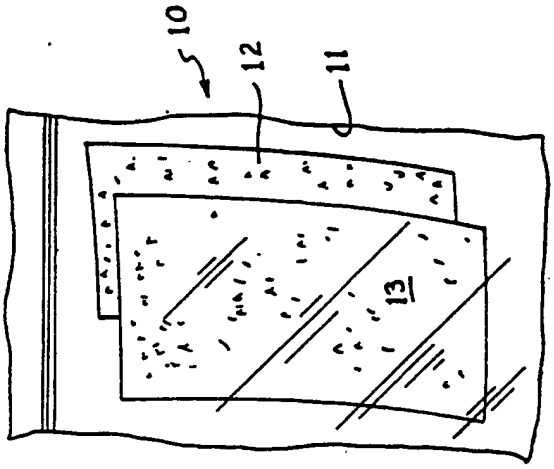


FIG. 1



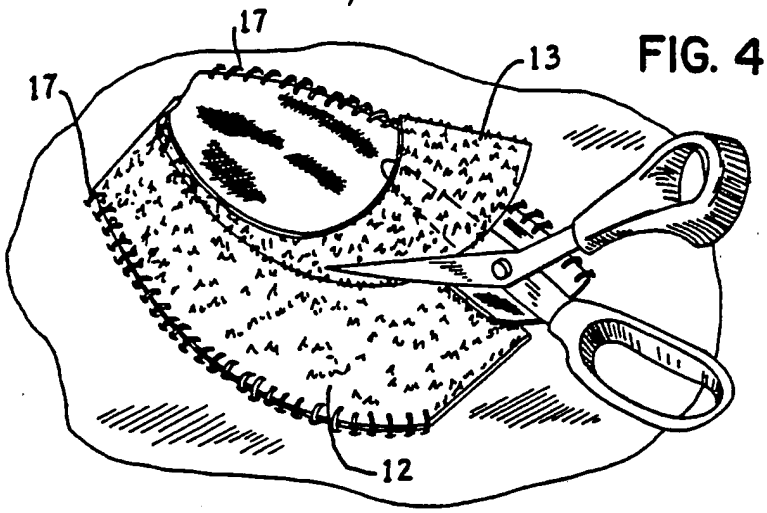


FIG. 4

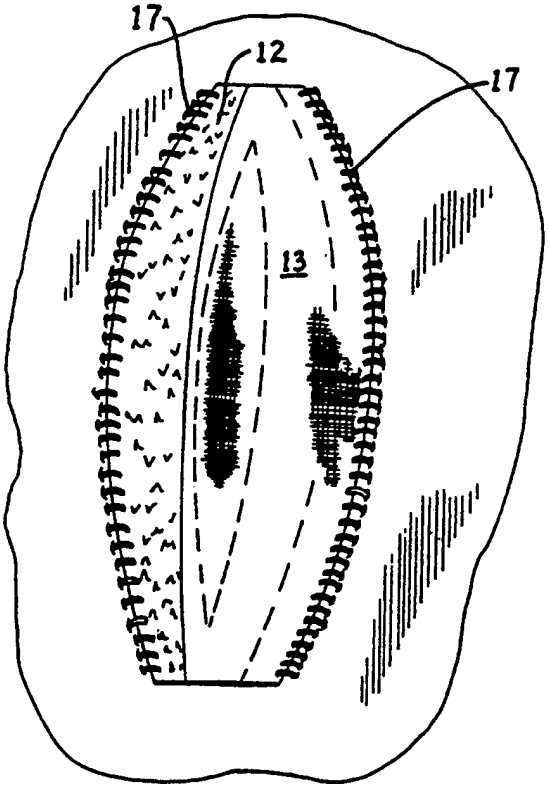


FIG. 5

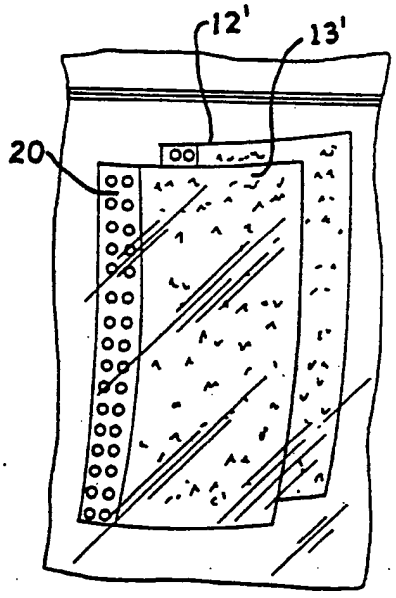


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application PCT/US90/00990

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5) : A61B 17/08

U S Cl : 606/215

II FIELDS SEARCHED

Minimum Documentation Searched 7

Classification System	Classification Symbols
U S	606/215,216

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched 8

III DOCUMENTS CONSIDERED TO BE RELEVANT *

Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
Y P	US,A 4,825,866 (PIERCE) 02 May 1989 See entire document.	1-5

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
19 March 1990	22 [illegible]

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